

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICEApplicants: Douglas J. Hilton *et al.*

Examiner: F. Hamud

Serial No.: 09/037,657

Art Unit: 1646

Filed: March 10, 1998

Docket: 10857Z

For: A NOVEL HAEMOPOIETIN RECEPTOR
AND GENETIC SEQUENCESAssistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C., 20231DECLARATION PURSUANT TO 37 CFR §1.132

I, Douglas J. Hilton, hereby declare as follows:-

1. I am an inventor of subject matter disclosed and claimed in U.S. Patent Application No. 09/037,657 (hereinafter referred to as the "application") and have read and understand, as far as possible, the Official Action issued by the United States Patent and Trademark Office on August 28, 2001.

2. In consultation with my patent advisors, I understand that Claims 20-27 and 35-48 are rejected under 35 USC §101 where the Examiner has alleged that the claimed invention is not supported by either a substantial, specific asserted utility or a well-established utility.

3. The present invention relates to the identification of a new haemopoietin receptor as well as genetic sequences encoding same. The new haemopoietin receptor is referred to in the specification as "NR6". The amino acid sequences defining NR6 are set forth in SEQ ID NOs:13, 15, 17, 19, 25 and 29 and are encoded by nucleotide sequences as set forth in SEQ ID NOs:12, 16, 18, 20, 24 and 28, respectively.

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4. The identification of NR6 as a new haemopoietin receptor and the observation that lack of NR6 is lethal during embryonic development or immediately after birth enables a range of diagnostic assays to be performed *in utero* and post-natally to determine the level of expression of NR6 genetic sequences and this is important in detecting potential birth defects or potential dysfunction to haemopoiesis.

5. The fact that NR6 has a role in haemopoiesis is clearly observed since a decrease in NR6 results in reduced blood cell production and we presume that an increase in NR6 will result in an increase in blood cell production.

6. It is important to appreciate that NR6 is a member of the haemopoietin receptor family. Other important and well characterized members of this family include receptors for IL-2, IL-3, IL-5, GM-CSF, GM-CSF, EPO and many others. Consequently, as all members of this family are involved in regulation of cell proliferation and differentiation, it is clear that NR6 would also be involved in similar activities. Consequently, the fact that NR6 can be reasonably predicted to be involved in haemopoiesis and has been shown to be involved in haemopoiesis by virtue of the fact that lack of NR6 results in a reduction in the number of blood cells, NR6 does provide a further diagnostic target, alone or in combination with other cytokine receptors, to assess the level of dysfunction or otherwise of the haemopoietin system in a subject.

7. Cytokines such as those listed above have pleiotropic activity and are involved in extensive physiological and genetic networks within the cell. The identification of a further member of the haemopoietic receptor family enables a more comprehensive and a more complete analysis of the complete haemopoietic potential of a cell and leads to the ability to define agonists and antagonists of these receptors. Recently, in fact, peptidomimetics were identified for two commercially available cytokines, i.e. erythropoietin and thrombopoietin and these mimetics were selected on the basis of peptides being capable of

binding to soluble versions of haemopoietin and thrombopoietin receptors. The identification of such receptors permits the identification of pleiotropic cytokines and the development of a range of therapeutic and diagnostic agents.

8. Consequently, as a person skilled in the art of cytokine biology and molecular biology, the utility of NR6 was immediately apparent to many as a useful diagnostic and therapeutic target and as a target for a potential agonist and antagonist.

9. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 13 May 2002

DJH

Douglas J. Hilton